UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,846	10/23/2003	Donald K. Jones	CRD5035CIP1	6702

27777 7590 09/29/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,846	JONES ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *7/27/06* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-3 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,702,418 to Ravenscroft in view of U.S. Patent No. 6,168,618 to Frantzen.

Ravenscroft discloses a stent delivery catheter that includes an elongate core member with proximal and distal cylindrical members (23) on the core (17). As shown more clearly in Figures 2,3, and 6, Ravenscroft explains that the cylindrical members (23) define a gap within which anchor members (20B) on a stent (20) are interlocked (column 6, lines 1-21). This configuration allows the stent to be pulled back into the outer sheath (24) after partial deployment (column 4, lines 30-36). Ravenscroft explains that the sheath (24) keeps the self-expanding stent (20) compressed onto the core so that the anchors are interlocked with the cylinders (23) (see column 6), and fails to include actuatable retaining rings.

Frantzen discloses another self-expanding stent delivery system that includes a self-expanding prosthesis (10) compressed onto an elongated core (22) member. Frantzen teaches that the system can be configured to release the rings in any desired order to prevent longitudinal displacement (column 1, lines 61-66 and column 5, lines 30-37). Frantzen teaches that the delivery system can include a sheath (column 2,

line 3). In lines 46-61 of column 4, Frantzen explains that the retaining rings (30) are severed by current supplied to electrode lead wires (32) to allow the self-expanding prosthesis (10) to expand. The rings remain attached the catheter (51) after they are severed (column 5, lines 44-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include actuatable retaining rings in the Ravenscroft delivery device, as Frantzen teaches that the actuatable rings increase the level of control over release of a vascular prosthesis so that proper placement can be achieved.

Regarding the new requirement for the anchor member to be at an end of the stent, the anchor members positioned in the gap are near the proximal end of the stent. The stent also has anchor members located at each end of the stent. These anchors are capable of being located within the gap between the cylindrical members. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the anchor members at the end of the stent within the gap, because applicant has not disclosed that this placement provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with anchor members located distal to the proximal end, because Ravenscroft discloses that this placement of the anchor performs the function of locking the stent with the introducer so that it can be repositioned.

2. Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of Frantzen, and further in view of US Patent No. 6,607,539 to Hayashi et al.

The modified Ravenscroft device fails to form the rings from material that melts in response to heat supplied by heating elements. Hayashi discloses another stent delivery system with retaining rings that are severed when electrical current is supplied to the them in a particular order (column 1, line 65-column 2). Hayashi teaches that the rings can be formed of material that melts and the actuation mechanisms are resistive heating elements (column 3, lines 43-53). Since the actuation mechanisms of Frantzen and Hayashi perform the same function of retaining a stent in a contracted state and releasing the stent upon supply of electrical current, the mechanisms are considered to be functional equivalents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use heat actuation instead of electrolytic erosion for severing the rings of the modified Ravenscroft device, as taught by Hayashi, as this is simply a substitution of functionally equivalent mechanisms.

3. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of Frantzen and Hayashi, as applied to claim 5 above, and further in view of US Patent No. 6,277,126 to Barry et al.

Ravenscroft, as modified by Frantzen and Hayashi above, includes all the limitations of claims 6-8 except for the retaining ring being a hot melt polymer filament. Hayashi does state that the retaining rings should be made from suture material (column 4, line 26), which includes many types of polymer filaments. Barry discloses another type of delivery system, in which an electric current is supplied to a resistive heating element. The heat is used to sever a coupling, thereby releasing a vascular implant. Here, Barry teaches that the coupling material can be a hot melt adhesive (which is inherently a polymer), because this type of material softens and

yields when exposed to heat. (See column 4, lines 29 – 40.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the retaining filaments of Hayashi from a hot melt polymeric material, as taught by Barry, as this material is suitable for forming retaining elements that yield with the application of heat in a vascular implant delivery system.

Response to Arguments

4. Applicant's arguments filed 8/24/06 have been fully considered but they are not persuasive. Applicant argues that Ravenscroft would be inoperable if the anchors at the end of the stent were placed within the gap between the cylindrical members. The stent includes anchoring structures along its entire length. Since the anchors at the end of the stent have the same structure as the other anchors, they are capable of being placed within the gap. The only modification would be moving the stent to a more distal location on the introducer. This modification would not cause the device to be inoperable. One of ordinary skill in the art would be capable of altering the placement of a stent on the introducer and determining the optimum placement of retaining rings on the modified Ravenscroft device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW
9/22/06 SKW

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER